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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/308,955 05/27/99 LUNDY

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EXAMINER

HM12/0605

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ART UNIT

PAPER NUMBER

1614

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06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/308,955

Applicant(s)

LUNDY et al.

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Mar 20, 2001

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-14 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

20) ☐ Other:

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#### **DETAILED ACTION**

The following is responsive to Applicant's election received March 20, 2001.

Applicant's election of "NSAID's" in subparagraph B of claims 4 and 11 is acknowledged.

#### ***Priority***

1. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

#### ***Information Disclosure Statement***

Applicant's Information Disclosure Statement received Feb. 3, 2000 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

#### ***Specification***

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

#### ***Claim Objections***

3. Claims 4, 9, 11, 12 are objected to because of the following informalities: in claim 4, lines 23-24 and line 12 (page 72); in claim 9, lines 11-12; in claim 11, line 37, line 6 (page 76), line 27 (page 76), the phrase "selected from the group consisting essentially of..." is improper Markush terminology. The phrase should be written as --selected from the group consisting of...--. Please refer to the MPEP 2173.05(h).

Furthermore, in claim 9, line 19, "per se" should be deleted. In claim 12, lines 17-18 (page 78), the phrase "which convey to a reader thereof of ordinary skill in the art" should be deleted. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague and indefinite because it is not clear to the Examiner what is meant by the phrase found at lines 13-15, beginning with "enteric-coated tablets" and ends with "to the stomach of said member."

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 5, 6, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Berger et al., 3,896,145.

Berger et al. teach the invention substantially as claimed. Specifically, Berger et al. teach pharmaceutical compositions useful as anti-inflammatory, analgesic and anti-rheumatic agents, the compositions comprising carbazole compounds which read on Applicant's claimed generic formula (I). The compositions are useful for oral or parenteral administration and may be in the form of tablets, capsules, suppositories, suspensions, solutions and emulsions. Please see col. 4-col. 7; col. 14, lines 1-12; col. 15, lines 8-24.

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7. Claims 1, 2, 5, 6, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Holtsinger et al. or Vasseur et al.

Holtsinger et al. teach a method of treating dogs suffering from degenerative joint disease, the method comprising administering to the dogs an effective amount (2.2 mg/kg) of carprofen. Results show that Carprofen is effective reducing the symptoms of the joint disease. Please see the abstract; page 141, "Materials and Methods".

Vasseur et al. disclose a method of treating dogs suffering from osteoarthritis, the method comprising administering to the dogs an effective amount (2.2 mg/kg) of carprofen. Results show that the dogs responded positively to the treatment. Please see the abstract; Discussion.

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of

each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 3, 4, 7, 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holtsinger et al. or Vassuer et al. or Berger et al, supra.

Holtsinger et al., Vasseur or Berger et al. as applied above.

Holtsinger, Vasseur or Berger do not disclose additionally administering an NSAID in combination with carprofen; however, Holtsinger and Vasseur disclose that carprofen belongs to the subclass of other conventionally known NSAID such as naproxen, ibuprofen, ketoprofen and fenoprofen. Please see Holtsinger, page 140, 1st paragraph under Introduction and Vasseur, page 807, second column, second full paragraph.

It would have been obvious to one of ordinary skill in the art to modify the methods and compositions of Holtsinger, Vassuer or Berger to combine an additional NSAID because Holtsinger and Vasseur teach that carprofen and other NSAID's are known in the art to be useful as analgesic, anti-inflammatory compounds. Modification to combine carprofen with the other NSAID's taught by Holtsinger and Vassuer, all of which are known to be useful for the same purpose, would have been obvious to one of ordinary skill in the art in view of the fact that the courts have held that "it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose" Kindly refer to In re Susi, 169 USPQ 423, 426 (CCPA 1971); In re Kerkhoven, 205 USPQ 1069 (CCPA 1980). Moreover, such a modification to combine would have been motivated by the reasoned expectation that the additive effect of the combination of carprofen and an NSAID would be successful in treating dogs suffering from degenerative joint disease or osteoarthritis.

In addressing the claims drawn to a package, the prior art of record does not disclose a packaged pharmaceutical composition comprising the claimed COX-2 inhibitory compounds along with instructional

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material; however, modification of known pharmaceutical compositions into kits with instructional material is not novel or unobvious and is well within the capability of the skilled artisan.

Additionally, the use of oral controlled release compositions is an art-recognized, result-effective variable and it would have been obvious to one of ordinary skill in the art to optimize it in the method and compositions of the prior art.

Finally, the use of the (S)-enantiomer of carprofen would have been obvious to one of ordinary skill in the art because isomers of a racemic compound are expected to have differing activities; one isomer is expected to more active than others (optically active isomer substitution was held to be obvious). See In re Anthony, 162 USPQ 594; In re Adamson, 125 USPQ 233.

### ***Conclusion***


Claims 1-14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM



June 4, 2001



Cybille Delacroix-Muirheid  
Patent Examiner Group 1600